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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,040	10/16/2006	Atsushi Miyawaki	P28994	3808

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
07/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/561,040	MIYAWAKI ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-22* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 14-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-8 and 11-22 are pending.

Applicants' amendments filed February 24 and April 28, 2010 are acknowledged. Applicants' response has been fully considered. Claims 8 and 11 have been amended, and claims 9-10 have been cancelled. Claims 1-7 and 14-22 are non-elected inventions and are withdrawn from consideration. Therefore, claims 8 and 11-13 are examined.

Withdrawn Informalities

2. The previous objection to the specification regarding the continuation data is withdrawn in view of applicants' amendment to the specification and applicants' response at page 11 in the amendment filed February 24, 2010.

Withdrawn Claim Objections

3. The previous objection to claim 8 is withdrawn in view of applicants' amendment to the specification and applicants' response at page 11 in the amendment filed February 24, 2010.

Withdrawn Claim Rejections - 35 USC § 112

4. The previous rejection of claims 9-10 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' cancellation of the claims in the amendment filed February 24, 2010.

Maintained Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 8 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8 and 11-13 are directed to an isolated DNA having a nucleotide sequence: the nucleotide sequence shown in SEQ ID NO: 13, 15, 17, or 19, or a nucleotide sequence comprising a deletion, substitution and/or addition of 1 to 60 nucleotides in the SEQ ID NO: 13, 15, 17 or 19, a recombinant vector or a transformant having the DNA; and an isolated DNA comprising a nucleotide sequence: a nucleotide sequence shown in SEQ ID NO: 13, 15, 17, or 19 (reads as full length and fragments of SEQ ID NO: 13, 15, 17 or 19), or a nucleotide sequence comprising a deletion, substitution and/or addition of 1 to 60 nucleotides in the SEQ ID NO: 13, 15, 17, or 19, and encoding a fluorescent protein.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional

characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification discloses a fluorescent protein from *favia favus* such as SEQ ID NO:1, its specific variants such as SEQ ID NO:12, 14, 16, 18 and 20 having mutations at specific positions, and the nucleotide sequences such as SEQ ID NO:2, 13, 15, 17, 19 and 21 that encoding the fluorescent proteins (pages 2-9 and Fig. 3), the specification does not disclose a genus of variants for polynucleotides having a deletion, substitution and/or addition of 1 to 60 nucleotides in the SEQ ID NO: 13, 15, 17 or 19 (claim 8, part (b)); for nucleotide fragments of SEQ ID NO:13, 15, 17 or 19 (claim 11, part (a)); or for polynucleotides having a deletion, substitution and/or addition of 1 to 60 nucleotides in the SEQ ID NO: 13, 15, 17 or 19 and encoding a fluorescent protein (claim 11, part (b)). While the specification provides SEQ ID NO:2, 13, 15, 17, 19 and 21 as the polynucleotides encoding the fluorescent proteins (i.e., SEQ ID NO:1, 12, 14, 16, 18 and 20), and indicates substitution at certain positions of the fluorescent protein can be made (e.g., positions 10, 12, 40, 54, 60, 62, 63, 69, 70, 87, 93, 109, 119, 121, 140, 144, 160, 196, 197 and 198; pages 27-29; Fig. 3), the specification does not provide an adequate written description for the whole genus of polynucleotide variants or fragments of SEQ ID NO: 13, 15, 17 or 19, when the functions of these polynucleotides are not indicated. Because the deletion, substitution and/or addition of 1 to 60 nucleotides can be made in any location of the

SEQ ID NO: 13, 15, 17 or 19 (claim 8, part (b)), substantial variations would occur within the whole genus of polynucleotides. Furthermore, the indication of substitutions at certain positions of the fluorescent proteins (pages 27-29; Fig. 3) does not provide sufficient description on structure to function/activity relationship for the claimed polynucleotide variants (including deletion or addition) that may or may not encode a fluorescent protein. Without sufficient guidance on the structure to function/activity in the polynucleotide variants, one skilled in the art could not predict which nucleotide sequence (e.g., the sequence having deletion or addition) would produce a functional polypeptide. Given the lack of a structure to function/activity relationship in the polynucleotide variants and lack of representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would not recognize Applicants were in possession of the claimed invention.

Response to Arguments

Applicants indicate that the specification provides the complete sequence structure for a nucleic acid which encodes a novel fluorescent protein from *favia favus* (specification at page 2, lines 7-17 and SEQ ID NOs: 1-2). Furthermore, the specification discloses the complete nucleic acid and amino acid sequence structures for five variants thereof, which variants are also fluorescent proteins (SEQ ID NOs: 12-13, 14-15, 16-17, 18-19, and 20-21), and mutations which may be made at twenty positions of SEQ ID NO: 1 (positions 10, 12, 40, 54, 60, 62, 63, 69, 70, 87, 93, 109, 119, 121, 140, 144, 160, 196, 197, 198), which mutations would encompass the deletion, substitution, and/or addition, of one to sixty nucleotides. Based at least on the foregoing, the specification describes the claimed subject matter in such a way as to reasonably

convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention (pages 12-13 of the response filed 2/24/10; pages 10-12 of the response filed 4/28/10).

Applicants' response has been fully considered. However, the arguments are not found persuasive because while the specification provides SEQ ID NO:2, 13, 15, 17, 19 and 21 as the polynucleotides (all contain 684 nucleotides) encoding the fluorescent proteins (i.e., SEQ ID NO:1, 12, 14, 16, 18 and 20; all contain 227 amino acids), and indicates substitution at certain positions of the fluorescent protein can be made (e.g., positions 10, 12, 40, 54, 60, 62, 63, 69, 70, 87, 93, 109, 119, 121, 140, 144, 160, 196, 197 and 198; pages 27-29; Fig. 3), the specification does not provide an adequate written description for the polynucleotide variants (especially the sequences having deletion or addition) or fragments of SEQ ID NO: 13, 15, 17 or 19 that may or may not encode fluorescent proteins as encompassed by the claims (claim 8, part (b); claim 11, part (a)). For example, all the identified nucleotide sequences (SEQ ID NO:2, 13, 15, 17, 19 and 21) contain 684 nucleotides that encode fluorescent proteins with 227 amino acids, and substitutions at certain positions of the fluorescent proteins are permitted (pages 27-29; Fig. 3). However, the specification has not provided sufficient description on the deletion or addition of 1 to 60 nucleotides to SEQ ID NO:13, 15, 17 or 19, and whether the resulting polynucleotide would encode a fluorescent protein. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 11 is rejected under 35 U.S.C. 102(e) as anticipated by Almond *et al.* (U.S. Pub. No. 2003/0157643 A1, filed December 9, 2002).

Almond *et al.* teaches a synthetic nucleic acid molecule comprising a nucleotide sequence that encodes a fluorescent protein, e.g., the DNA sequence of SEQ ID NO:21 encoding a humanized green fluorescent protein (Figs 2A-2B; paragraph [0029]). The nucleotide sequence of SEQ ID NO:21 has sequence identity of 81.3%, 80.8%, 79.9% and 79.9%, respectively, to the nucleotide sequence of SEQ ID NO:13, 15, 17 and 19, respectively (See the sequence match sent 3/3/09). Since SEQ ID NO:21 comprises the nucleotides 1-11 and 359-416 of instant SEQ ID NO:13 (fragment of SEQ ID NO:13; a nucleotide sequence shown in SEQ ID NO:13), SEQ ID NO:21 reads on part (a) of claim 11.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
July 9, 2010